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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,000	01/24/2005	Daryl Rees	92773	8840

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EXAMINER	
WEBB, WALTER E	

ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,000	REES ET AL.	
	Examiner	Art Unit	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9* is/are pending in the application.

4a) Of the above claim(s) *1-4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 10/26/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103--previous

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 5-7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. (supra) in view of Louvel et al. (Trends in Pharmacological Sciences 1997).

The claims now depend from newly added claim 9. The rejection now applies to claims 9 and 5-7.

Xia et al. teaches a method of treating conditions that are characterized by a deficiency in the number and function of membrane bound receptors by administering saponins and sapogenins (see abstract). The reference teaches that sarsasapogenin (SaG), in particular, may be mediated through increases in the levels of one or more neurotrophic factors (see pg. 11, lines 30-31).

Xia et al. does not teach treatment of amyotrophic lateral sclerosis (ALS).

Louvel et al. teaches that neurotrophic factors have been used to treat ALS (see pg. 199, right col., last paragraph; see also pg. 202, left col. paragraphs 1-5). While some efforts have been unsuccessful, the reference teaches that "other neurotrophic factors may also be of use in ALS", such as glial derived growth factor, neurotrophin-3 and cardiotrophin. (see pg. 202, left column, 5th paragraph). Louvel et al. does not teach the use of sarsasapogenin.

In KSR v. Telefex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, "obviousness to try" such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to treat ALS using neurotrophic factors. Accordingly, it would have been obvious to have used sarsasapogenin in a method for treating ALS, since sarsasapogenin treats conditions that are characterized by a deficiency in the

number and function of membrane bound receptors and mediates increases in the levels of one or more neurotrophic factors. It would have also been obvious to combine sarsasapogenin with neurtrophic factors since they would be used for the same purpose.

2) Claims 5-7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. (GB 2 335 599, published 9/29/1999) in view of Roberts (US 4,831,033). The claims now depend from newly added claim 9. The rejection now applies to claims 9 and 5-7.

Xia et al. teaches a method of treating conditions that are characterized by a deficiency in the number and function of membrane bound receptors by administering a pharmaceutical composition saponins or sapogenins (see abstract, see also claim 4, at pg. 28). Disease conditions include include Alzheimer's disease, senile dementia, Parkinson's disease (**claim 8**), Lambert Eaton disease etc. (see id.). Saponins and sapogenins include sarsasapogenin (**claims 1-5**) (see id. and pg. 28, clm. 3 and 4). The composition is taught to be present with one or more additional active agents (**claim 6**) (see pg. 28, clm. 3). Xia et al. also teaches that the sapogenin compounds treat Alzheimer's disease by selectively increasing muscarinic M_1 receptors (see pg. 23, lines 23-26), thereby **increasing the activity of the neurotransmitter acetylcholine** (see pg. 2, lines 5-21).

Xia et al. differs from the instant claims insofar as it does not teach treating ALS.

Roberts teaches that Alzheimer's disease is similar to ALS insofar as both are taught to be treated by **increasing the activity of acetylcholine** by administering a cholinesterase inhibitor that decreases its rate of breakdown (see Summary of the Invention at col. 3, lines 44-52; see also col. 3, lines 14-17). Roberts teaches amodiaquin as the cholinesterase inhibitor (see col. 3, line 66).

Roberts does not teach the use of sarsasapogenin.

It would have been obvious to a person having ordinary skill in the art to use the sarsasapogenin of Xia et al. to treat ALS since ALS and Alzheimer's disease are known to be treated the same, as taught by Roberts. Since the sarsasapogenin of Xia et al. treats Alzheimer's disease by increasing the activity of acetylcholine through increased muscarinic receptors, the artisan would have reasonably expected it to treat ALS, which is also known to be treated via increased acetylcholine activity.

Generally, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art. See MPEP 2144.06. Thus, it would have also been obvious to combine the sarsasapogenin of Xia et al. with the cholinesterase inhibitor of Roberts, as per **claim 7**, to treat ALS, since they would both serve to enhance of nerve function in the ALS patient.

Response to Arguments

Applicant argues Xia et al. does not predict that the same agent will treat neuronal disorders in another part of the body, e.g. motoneurons in the case of ALS, and that the biochemical and neuronal function and structures on the disease and its progression are too diverse and generally too unpredictable to allow such expectations. However, applicant provides no evidence to support the unpredictability of treating ALS. Nevertheless, it would have been obvious to try since sarsasapogenin functions by mediating increases in the levels of one or more neurotrophic factors and neurtropic factors have been used to treat ALS. Louvel does not teach away from using neotrophic factors as a class, since it teaches that other neurotrophic factors may also be of use in ALS, such as glial derived growth factor, neurotrophin-3 and cardiotrophin.

In regard to the use of Xia and Roberts, applicant argues that "[t]his very lukewarm endorsement of the underlying rationale in such therapy design is certainly not enough to render it obvious". However, Roberts teaches treating ALS by increasing the activity of the neurotransmitter acetylcholine. Since, the sarsasapogenin of Xia et al. functions by increasing the activity of the neurotransmitter acetylcholine, it would have been obvious to use it to treat ALS.

Conclusion

`THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612